UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

Walters et al. v. City of Flint et al.	Case No. 5:16-cv-10164-JEL-MKM Honorable Judith E. Levy

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PLAINTIFFS' CONSOLIDATED RESPONSE TO VNA'S MOTION TO EXCLUDE THE TESTIMONY AND REPORTS OF AARON SPECHT, PH.D.

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INTRODUCTION

Dr. Aaron Specht, Ph.D. will testify at trial on behalf of four bellwether plaintiffs (collectively "Plaintiffs"), that the lead that has accumulated in Plaintiffs' bones reflects a "substantial exposure" to lead. His testimony goes directly to Plaintiffs' claim that exposure to lead in Flint's water during the Flint Water Crisis caused them to be lead poisoned.

To be sure, Dr. Specht plays a narrow role: Plaintiffs' other experts will testify that lead is toxic and can be especially poisonous to children (Dr. Graziano); that the Plaintiffs would have received a sufficient dose of lead from Flint's water to cause them to be lead poisoned (Dr. Michaels); that they in fact are lead poisoned (Dr. Bithoney); that Plaintiffs' have suffered neurocognitive effects and will, more likely than not, cause them to suffer further deficits in the future (Dr. Krishan); and that those deficits will cause Plaintiffs lost economic opportunities throughout their lives (Dr. Crakes). Yet, the unique circumstances of this litigation call for an expert who can show that the children have in fact been substantially exposed to lead.

Indeed, one of the characteristics of lead poisoning is that a traditional blood testing method of measuring lead exposure is limited by lead's short half-life of about one month in the blood. This difficulty is compounded by the exponentially shorter half-life of lead in children, which is just one week. His testimony will be especially significant in this case because misinformation and lack of sufficient

access to blood testing critically hampered the ability of Flint residents (including Plaintiffs) to obtain accurate measurements of lead levels as a result of exposure from Flint's tap water during the Flint Water Crisis. Dr. Specht's reliable and widely accepted methodology for measuring lead accumulation in bones will aid the jury in understanding the extent of Plaintiffs' exposure. This is because lead has a much longer half-life in bones, and so bone lead testing can paint a fuller picture of each Plaintiff's exposure. His methodology uses a scan with a portable x-ray fluorescence ("pXRF") scanning device to produce a highly accurate reading of the accumulated lead in a subject's tibia. He has tested subjects in several countries and routinely published his results in peer-reviewed scientific journals.

Defendants Veolia North America, LLC, Veolia North America, Inc., and Veolia Water North America Operating Services, LLC (collectively, "VNA") move to exclude Dr. Specht pursuant to Federal Rules of Evidence 702 and 403, and *Daubert v. Merrill Dow Pharms.*, 509 U.S. 579 (1993), because, in their view, he uses an unreliable testing methodology and offers unreliable opinions. The truth, however, is simply that VNA disagrees with Dr. Specht's opinions and has identified certain subjects more appropriate for cross-examination. It is beyond cavil that the lines of inquiry a litigant may pursue on cross-examination do not furnish a basis for wholesale exclusion.

Additionally, VNA believes Dr. Specht's opinions are significantly more prejudicial than probative and likely to confuse the jury and that he therefore should be excluded under Rule 403 because the results of his bone lead testing do not trace those lead levels to any potential cause. This challenge simply mistakes Dr. Specht's limited role. Dr. Specht is not Plaintiffs' only expert; he is not being offered to prove every aspect of Plaintiffs' case on causation. In short, his testimony is only one piece of a larger puzzle.

Accordingly, VNA's motion should be denied.

BACKGROUND

I. Dr. Specht is eminently qualified.

Dr. Specht is a board-certified medical physicist who obtained a Ph.D. in medical physics from Purdue University in 2016. Ex. 1, Specht Report, at 24; Ex. 2, Specht CV. After three years of postdoctoral training at the Harvard T.H. Chan School of Public Health in Occupational and Environmental Health and Epidemiology, Dr. Specht became a research associate there. Ex. 1, Specht Report, at 24; Ex. 2, Specht CV. He also currently serves as the Director for the HSPH NIEHS Trace Metals Lab in the Department of Environmental Health. Ex. 1, Specht Report, at 24; Ex. 2, Specht CV. He has published 20 peer-reviewed articles in scientific journals, many on pXRF testing. *See* Ex. 1, Specht Report, at 24–27.

II. Bone lead testing offers significant advantages likely to help a jury comprehend the extent to which Plaintiffs have suffered from lead poisoning.

Dr. Specht's pXRF and bone lead testing of the Plaintiffs offers significant advantages and will help the jury understand crucial disputed issues at trial.

Even after a series of public health interventions in the 1980s and 1990s reduced overall lead exposures, "it was determined that ever lower levels of lead exposure continued to show these drastic influences on neurodevelopment, particularly in children." *Id.* at 1–2.[1] Although lead dust can be ingested, "water soluble lead actually increases the ability of the body to metabolize and ultimately absorb the ingested lead. Thus, lead in water is a particularly dangerous source of exposure during development." *Id.*[2]

"The primary means of surveilling lead exposure in communities relies on widespread blood testing." *Id.* at 3. However, in some situations blood-lead testing's

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[1] Citing R.L. Canfield et. al., *Intellectual Impairment in Children with Blood Lead Concentrations Below 10 μg per Deciliter*, 348(16) New Eng. J. Med. 26 (2003) ("Canfield 2003"); B.P. Lanphear et. al., *Low-Level Environmental Lead Exposure and Children's Intellectual Function: An International Pooled Analysis*, 113(7) Envt'l Health Perspectives 894-99 (2005) ("Lanphear 2005); T.A. Jusko et. al., *Blood Lead Concentrations < 10 Microg/dL and Child Intelligence at 6 Years of Age*, 116(2) Envt'l Health Perspectives 243–48 (2008) ("Jusko 2008"); B.P. Lanphear et. al., *Low-level Lead Exposure and Mortality in US Adults: A Population-Based Cohort Study*, 3(4) Lancet Pub. Health e177-e184 (2018) ("Lanphear 2018").

[2] Citing U.S. Dept. of Health and Human Servs., Agency for Toxic Substances and Disease Registry, *Toxicological Profile for Lead*, 528, (2007), available at https://www.atsdr.cdc.gov/toxprofiles/tp13.pdf.

"capabilities as a biomarker of exposure are severely lacking." *Id.*[3] This is in part because a blood-lead level "is highly linked with turnover of red blood cells in the body, as red blood cells are the primary carriers of lead in blood." *Id.* And the half-life of lead in the blood of children is "less than a week." *Id.* As a result, "the measurement [of lead] from blood is incredibly time sensitive." *Id.*[4] Any given blood-lead measurement, particularly one taken in isolation and not part of series of consistent measurements tracking the child's blood-lead, faces severe limitations in accuracy. *Id.* "Given the time frame of peak exposures from the lead crisis and the unavailability of widespread testing in the community until after this time, it is highly unlikely that many members of the community had accurate measures of their exposure taken using a blood lead test." *Id.*

Measuring lead in bone, however, offers significant advantages. "When lead gets in the body, it acts similarly to calcium, as they have similar binding properties." *Id.* (citing Ex. 4, Rabinowitz 1991). Lead tends to replace calcium in bone, which makes it an "excellent marker of exposure." *Id.* at 4. Further, unlike tracking

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[3] Citing Ex. 4, M.B. Rabinowitz, *Toxicokinetics of Bone Lead*, 91 Envt'l Health Perspectives 4 (1991) ("Rabinowitz 1991").

[4] Citing Ex. 5, A.J. Specht & Y. Lin et. al., *XRF-Measured Bone Lead (Pb) as a Biomarker for Pb Exposure and Toxicity Among Children Diagnosed with Pb Poisoning*, 21(4) Biomarkers 347–52 (2016) ("Specht 2016"); Ex. 6, A.J. Specht & M. Weisskopf et. al., *Childhood Lead Biokinetics and Associations with Age Among a Group of Lead-Poisoned Children in China*, J. Exposure Sci. & Envt'l Epidemiology (2018) ("Specht Weisskopf 2018").

exposure via blood-lead, "a single measurement of bone lead reflects the lead exposure during a time period of potential exposure from an acute or chronic source in an individual's past (I.e. the water crisis)." *Id.* "Thus, we can use bone lead to identify lead exposure that was missed due to the poor temporality and unavailability of widespread blood lead testing from years prior." *Id.*

III. Dr. Specht uses pXRF, a reliable methodology, to measure Plaintiffs' bone lead.

A. How XRF works.

"Bone lead can be measured in a variety of ways, but the most successful and least invasive method is a tool utilizing x-ray fluorescence (XRF)." *Id.*[5] "XRF has been used for years to determine the bone lead level of individuals in a variety of different settings." *Id.*[6] "In XRF, an X-ray source generates a photon beam that

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[5] Citing L. Wielopski & K.J. Ellis et. al., *In Vivo Bone Lead Measurements: A Rapid Monitoring Method for Cumulative Lead Exposure*, 9(3) Am. J. Ind. Med. 221–26 (1986) ("Wielopski 1986"), H. Hu, F.L. Milder & D.E. Burger, *X-ray Fluorescence: Issues Surrounding the Application of a New Tool for Measuring Burden of Lead*, 49(2) Envt'l Res. 295–317 (1989) ("Hu 1989"), A.C. Todd et. al., *Validation of X-ray Fluorescence-Measured Swine Femur Lead Against Atomic Absorption Spectrometry*, 109(11) Envt'l Health. Perspectives 1115-19 (2001) ("Todd 2001").

[6] Citing Wielopolski 1986; M. Bleecker et. al., *Relationship Between Bone Lead and Other Indices of Lead Exposure in Smelter Workers*, 77 Toxicology Letters 241–48 (1995) ("Bleecker 1995); Ex. 7, F.E. McNeill et. al., *109Cd K X Ray Fluorescence Measurements of Tibial Lead Content in Young Adults Exposed to Lead in Early Childhood*, 57(7) Occupational Envt'l Med. 465–71 (2000) ("McNeill 2000"), R. Grashow et. al., *Cumulative Lead Exposure in Community-Dwelling Adults and Fine Motor Function: Comparing Standard and Novel Tasks in the VA*

passes through the sample," thereby "releasing fluorescence, characteristic of the element of each atom." *Id.* "The fluorescence in the form of secondary X-rays is measured by a radiation spectrometer and the rate of determination of these secondary rays gives the elemental concentration present in the sample." *Id.*

There are two applicable testing energies for XRF devices: K-shell (high energy) and L-shell (low energy). *See id.* at 5. The two "shells" are "reflective of the electron orbitals in which the measurement arose." *Id.* There are also some minor differences—for example, whether a radioisotope source is required—but "[b]oth have been used successfully for decades in measurement of bone lead." *Id.*

B. The pXRF device Dr. Specht used, as compared to KXRF devices.

Initially, scientists used KXRF devices to measure bone lead. *See id.* They "were incredibly large, difficult to obtain, difficult to operate, and took a significant amount of time for each measurement." *Id.* Indeed, they were about the size of a recliner, required a radioisotope source, used higher energy X-rays, took about 30 minutes for a single scan, and the nearest device is located at Purdue University, a five-hour drive from Flint. *See* Ex. 3, Specht Dep., at 225:2–226:7, 293:3–15.

Normative Aging Study, 35 Neurotoxicology 154-61 (2013) ("Grashow 2013"); Ex. 17, A.J. Specht, Y. Lin, & M. Weisskopf et. al., *Bone Lead Levels in an Environmentally Exposed Elderly Population in Shanghai, China,* 626 The Sci. of Total Env't 96–98 (2018) ("Specht Lin 2018").

However, "[m]easurement of bone lead has become much more convenient as the capabilities of the XRF technology has improved." Ex. 1, Specht Report, at 5. This is due to improvements in L-shell detection technology. *Id.* While L-shell devices were originally comparable to K-shell devices, a series of improvements in the early 2000s "vastly improved in both the maximum counts per second (resolving time) and energy resolution, which would drastically lower the detection limits and, most importantly, the measurement times with these devices." *Id.*

"The current standard L-shell XRF utilizes a portable form factor and boasts a 3-minute measurement time to achieve equivalent detection limits to conventional XRF devices." *Id.*[7] "This allows for easy, convenient measurements of bone lead in field environments and the ability for widespread testing for cumulative lead exposure." *Id.* at 6. "The current portable XRF measures the same bone lead measurement as has been done decades prior. This has been verified in theoretical, human, animal, and lab settings using multiple methodologies for validation." *Id.*[8]

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[7] Citing Ex. 7, A.J. Specht & M. Weisskopf et. al., *Portable XRF Technology to Quantify Pb in Bone In Vivo*, Biomarkers 398032 (2014) ("Specht Weisskopf 2014").

[8] Citing H. Nie & S. Sanchez et. al., *In Vivo Quantification of Lead in Bone with a Portable X-ray Fluorescence System—Methodology and Feasibility*, 56(3) Phys. Med. Biol. N39-51 (2011) ("Nie 2011"); Ex. 8, Specht Weisskopf 2014; Ex. 5, Specht 2016; Ex. 10, A.J. Specht & C.N. Parish et. al., *Feasibility of a Portable X-ray Fluorescence Device for Bone Lead Measurements of Condor Bones*, 615 The Sci. of Total Env't 398-403 (2018) ("Specht Parish 2018"); Ex. 11, A.J. Specht & A.S. Dickerson et. al., *Comparison of Bone Lead Measured Via Portable*

C. The built-in uncertainty measurement.

Dr. Specht's methodology includes a built-in measurement of "uncertainty." *See id.* at 14, 16, 17, 19; Ex. 3, Specht Dep., at 162:22–163:17. Regarding how "uncertainty" is "derive[d]," Dr. Specht explained that it is produced by the "fitting program itself." Ex. 3, Specht Dep., at 131:10–15. The MATLAB program uses data obtained from the pXRF device to analyze "the Gaussian fit of the lead signal itself and using those net counts and the air associated with the net counts through air propagation." *Id.* at 131:15–21. Put more simply, uncertainty is "proportional to the bone lead measurement." *See id.* at 132:18–133:9. The "background counts," which are "proportional to the soft tissue thickness,"[9] also affect the uncertainty measure. *See id.* at 131:22–132:2, 132:18–133:9. The factors work together, so that when both values are higher—"when you have higher net counts and a higher background"—there will be "a proportionally higher uncertainty." *Id.* at 133:7–9.

VNA inquired whether there was "acceptable level of uncertainty," and Dr. Specht answered that an uncertainty level "over 10 or much greater than 15" would be concerning. *Id.* at 133:12–18. At that point, "the uncertainty itself would be really

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Xray Fluorescence Across and Within Bones, 172 Envt'l Res. 273-78 (2019) ("Specht Dickerson 2019"); Ex. 12, A.J. Specht & K.E. Kirchner et. al., *Lead Exposure Biomarkers in the Common Loon*, 647 The Sci. of the Total Env't 639-44 (2019) ("Specht Kirchner 2019").

[9] Soft tissue thickness is automatically estimated by the pXRF device based on feedback during the scan. Ex. 3, Specht Dep., at 163:8–11.

having an impact on the measurement, assuming that the scan itself was lower than the uncertainty." *Id.* at 133:18–21. In other words, a very high uncertainty might be higher than the bone scan result itself. However, "[a]s long as the scan—the lead measurement, the concentration, is higher than the uncertainty, we're typically fairly confident in the results." *Id.* at 133:21–24.

D. Dr. Specht and his colleagues have refined the procedural settings over time, producing increasingly accurate results.

Dr. Specht has been researching, testing, and refining pXRF his entire professional career. He articulated some initial calibrations for the pXRF device and compared them with KXRF technology in a 2014 peer-reviewed article. *See* Ex. 8, Specht Weisskopf 2014, at 7. That article explained that "[the] data set shows excellent agreement of bone Pb concentrations for cadaver bones at thickness of 1.3 and at 4.1 millimeters while the agreement deteriorates at 5.6 millimeters." *Id.* The 2014 paper concluded:

> We have validated an advanced portable XRF system for *in vivo* bone Pb measurements and demonstrated the validity of using such a system to accurately quantify lead in bone with soft tissue thicknesses up to 4-5 mm. The detection limit of the device with 4 mm of soft tissue is approximately the same as the detection limit of the KXRF systems, and the novel analysis method provides a better correlation for Pb quantification in bone samples. This device now has vast applicability in lead exposure assessment in clinical and research settings.

Id. at 7–8.

He further tested those parameters in a 2016 study of lead-poisoned children in China. That article found a general validation of pXRF testing but noted that further research was necessary for pediatric populations. *See* Ex. 5, Specht 2016, at 6–7. The 2016 paper noted a "limited ability of the portable XRF with current calibration methods to quantify bone pB in children." *Id.* at 6. However, the 2016 study was consciously aware of "the simple calibration of the portable XRF device used in this study," and so recognized that "future measurements of children using this technology may be feasible, but further investigation on the effect of bone composition and an improved calibration would be necessary to obtain more accurate results." *Id.* at 7.

Dr. Specht also published an article in 2019 based on 2016 testing. At the outset that article noted that, following the 2016 testing, additional studies were necessary. *See* Ex. 11, Specht Dickerson 2019, at 2. Although Dr. Specht continued to make refinements after the 2019 study (see below), the 2019 study found that the "average uncertainty for the pXRF measurements" was "similar to the uncertainty associated with conventional KXRF systems in pediatric populations," and thus concluded that, as a general matter, "pXRF can be used to effectively identify Pb exposed individuals from unexposed subjects in a study." *Id.* at 9.

During the 2016 study of children in China, Dr. Specht and his team used an abbreviated two-minute scan for the subjects. In 2016, Dr. Specht and his team "had

not optimized the methodology, as evident by our choice of using two minutes rather than three minutes in the procedures for this study." Ex. 3, Specht Dep., at 258:9–259:4. After 2016, Dr. Specht revised the methodology and, in pertinent part, increased the duration of the scan from two to three minutes. This greatly enhanced the accuracy of the measurements. As Dr. Specht explained: If they had used three minutes they "would have been able to identify a much stronger association." *Id.* at 259:5–12. As he said when VNA attempted to raise the issue again, the "procedural differences account for a lot of that." *See id.* at 298:5–22; *see also id.* at 300:6–18.

Additionally, Dr. Specht discovered that the 2014 and 2016 settings were "vastly overestimating the background using a region of interest calculation, which is why those numbers were so much different for the larger concentration—or larger soft tissue thicknesses." *See id.* at 247:10–15. "So if you looked at it, it was only the highest soft tissue thickness [those well over 5.6 mm] that was having the numbers be off by such a wide margin, and that was because of the overestimation of background subtraction, which was that methodology." *Id.* at 247:16–21.

In a subsequent study, Dr. Specht was able to further validate the pXRF device. As Dr. Specht testified, this study "show[ed] a direct comparison between the portable XRF and KXRF that has a significant correlation between the two with fairly good agreement." *Id.* at 408:14–17. Accordingly, "[t]his study was very conclusive in saying that it did support using the pXRF in studies of bone lead." *Id.*

at 431:6–8. The study concluded: "The portable XRF is a valuable tool for population studies on Pb exposure, avoiding many of the disadvantages of the KXRF measurements, and the method is ready to be used for large-scale population studies where the KXRF is not accessible or not practical." Ex. 9, X. Zhang et. al., *Evaluation of a Portable XRF Device for In Vivo Quantification of Lead in Bone Among a U.S. Population*, 753 Sci. of Total Env't 142351, 7 (2021) ("Zhang 2021").

Dr. Specht also has validated pXRF in subsequent animal testing. In a study involving condor bones, the pXRF's ability to accurately determine an amount of bone lead was compared to "inductively coupled plasma mass spectrometry" ("ICP-MS"), in which bone lead is measured by chemically digesting bone in nitric acid. Ex. 3, Specht Dep., at 362:9–364:1. ICP-MS, though not an option for living subjects, "has detection limits in the parts per trillion range, which is very, very accurate." *Id.* at 363:23–364:1. Notably, Dr. Specht's study found a "good correlation" between the accuracy of ICP-MS and pXRF. *Id.* at 370:15–20. After all, "[c]alibration approaches have been developed [for the pXRF] to correct for soft tissue thickness in the measurement." Ex. 10, Specht Parish 2018, at 399. In a similar study involving loons, Dr. Specht concluded that the "results clearly demonstrate that portable XRF measurements of lead in bone have good comparability to ICP-MS measures of lead in bone." Ex. 12, Specht Kirchner 2019, at 642.

IV. The Plaintiffs' bone lead measurements.

Measurements were conducted for each bellwether Plaintiff between 2019 and 2020 using the standard operating procedures Dr. Specht created. *See* Ex. 3, Specht Dep., at 43:5–14. For each Plaintiff, "[b]one lead was measured from [the Plaintiff's] leg using a pXRF device." Ex. 1, Specht Report, at 14, 16, 17, 19.

His report specifies that these procedures were followed for each Plaintiff:

> We performed quality control checks to ensure the device has the appropriate settings for the x-ray tube of 50 kV and 40 uA using a filter of silver and iron by verifying the spectral profile against fake (phantom) bones made in our lab. We used these standard phantoms with known lead level as a basis for the concentration we derived from [each Plaintiff's] measurement. Similarly, the measurement uncertainty indicated the device was operated appropriately and the other elemental peaks verified presence of the bone.

Id. at 14, 16, 17, 19. The pXRF device is calibrated every few months. *See* Ex. 3, Specht Dep., at 87:11–22, 217:5–11.

[redacted]

[10] There was a typographical error in Dr. Specht's report. *See* Ex. 3, Specht Dep., at 492:23–494:2.

[redacted]

V. Dr. Specht's opinions regarding Plaintiffs' bone lead levels.

Dr. Specht opines, based on the pXRF test results, that each Plaintiff has a "substantial exposure" to lead. *See id.* at 14, 16–20. Dr. Specht was able to compare Plaintiffs' bone lead measurements with "[r]eference studies of bone lead [that] have been completed in a few comparable groups for recent environmental exposures, legacy leaded gasoline exposures, and within groups of communities with known exposure sources from industry." *See id.* at 6.

For instance, a study of "lead poisoned children in China" found that the exposed group had very high levels through their consumption of 100% lead powder (a "median and standard deviation of bone lead was 12 ± 26 ug/g bone mineral"), while the control group there did not ("a median value of -1 ± 4 ug/g bone mineral"). *Id.* (citing Ex. 5, Specht Lin 2016, Ex. 6, Specht Weisskopf 2018). "Similarly, a recent population survey of children between 6-19 years of age in Ontario, Canada found bone lead levels to be 0.63 ± 1.0 ug/g bone mineral (average ± standard deviation)." *Id.* (citing Ex. 7, McNeill 2017).

Thus, Dr. Specht can reliably opine that Plaintiffs' bone lead measurements are consistent with elevated bone lead. "Even though the majority of their blood lead levels from the population in Flint are only slightly elevated with respect to the CDC reference levels, many of their bone lead levels are more consistent with that of lead poisoned children in the study in China." *Id.* at 7 (citing Ex. 5, Specht Lin 2016, Ex. 6 Specht Weisskopf 2018). The discrepancy likely owes to "the inaccuracy of the blood lead due to the timing and chronic nature of this exposure from the water crisis in particular." *Id.* Moreover, the Plaintiffs' bone lead results were in line with general "bone lead results from Flint" that "were 6.8 times higher on average than children in Ontario." *Id.*

Dr. Specht's narrow but necessary role is limited to explaining to the jury what he found when he tested the Plaintiffs for lead in their bones—nothing more, nothing less.

ARGUMENT

VNA argues that the Court should exclude Dr. Specht's testimony for two reasons. First, in its view, Dr. Specht's methodology and opinions are unreliable and thus inadmissible under Rule 702 and *Daubert v. Merrell Dow Pharm.*, 509 U.S. 579 (1993). VNA's argument is based on little more than its mere disagreement with Dr. Specht's opinions, which is not a basis for excluding his testimony. Second, VNA believes that Dr. Specht's testimony would be more prejudicial than probative,

requiring the Court to exclude it pursuant to Rule 403. However, VNA's argument mistakes the narrow role for which Plaintiffs are offering Dr. Specht, and there exist more sufficient and far less drastic ways for for VNA to address its concerns about Dr. Specht's testimony than excluding it completely. For instance, the Court can direct Plaintiffs to present to his testimony in a manner that avoids confusion or undue prejudice, *see Gissantaner*, 990 F.3d at 470, and can instruct the jury as necessary. *Cf. Williams v. Illinois*, 567 U.S. 50, 80–81 (2012).

Accordingly, the Court should deny VNA's motion.

I. Dr. Specht's testimony is admissible under Federal Rule of Evidence 702.

The main thrust of VNA's motion is its erroneous belief that Dr. Specht's testimony must be excluded under Federal Rule of Evidence 702 because his methodology, and therefore his opinions are unreliable.[11] VNA does not challenge Dr. Specht's qualifications to testify, or whether his testimony "fits' the facts of the case. While VNA may have identified potential subjects of cross-examination, the authority Veolia cites in support of its claims does not justify wholesale exclusion, an extreme remedy that the Sixth Circuit has repeatedly held is "the exception rather than the rule." *In re Scrap Metal Antitrust Litig.*, 527 F.3d at 530.

[11] Plaintiffs note that VNA does not challenge Dr. Specht's qualifications at all. Nor can it; Dr. Specht is unquestionably qualified. *See supra* at 3.

A. Legal standard under Federal Rule of Evidence 702.

Federal Rule of Evidence 702 governs the admissibility of expert testimony in federal courts. *Daubert*, 509 U.S. at 588. Under Rule 702, "a proposed expert's opinion is admissible, at the discretion of the trial court, if the opinion satisfies three requirements." *In re Scrap Metal Antitrust Litig.*, 527 F.3d 517, 528–29 (6th Cir. 2008). "First, the witness must be qualified by 'knowledge, skill, experience, training, or education.' Second, the testimony must be relevant, meaning that it 'will assist the trier of fact to understand the evidence or to determine a fact in issue.' Third, the testimony must be reliable." *Id.* at 529 (quoting Fed. R. Evid. 702).

The watchword of a court's *Daubert* analysis is reliability. After all, the "overarching goal" is "assessing the 'scientific validity and thus the evidentiary relevance and reliability' of the principles and methodology underlying the proposed expert testimony." *United States v. Langan*, 263 F.3d 613, 621 (6th Cir. 2001) (quoting *Daubert*, 509 U.S. at 594–95). "Four inquiries guide the reliability analysis: Is the technique testable? Has it been subjected to peer review? What is the error rate and are there standards for lowering it? Is the technique generally accepted in the relevant scientific community?" *United States v. Gissantaner*, 990 F.3d 457, 463 (6th Cir. 2021); *accord Nelson v. Tennessee Gas Pipeline Co.*, 243 F.3d 244, 251 & n.5 (6th Cir. 2001).

The inquiry isn't a "definitive checklist or test." *Daubert*, 509 U.S. at 593. On the contrary, the inquiry is inherently a "'flexible one,'" *Nelson*, 243 F.3d at 251 (quoting *Daubert*, 509 U.S. at 594), and must of course "be 'tied to the facts' of a particular 'case.'" *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 150 (1999) (quoting *Daubert*, 509 U.S. at 591). It is therefore unsurprising that "no single factor [above] disposes of a reliability inquiry." *Ruiz-Troche v. Pepsi Cola of P.R. Bottling Co.*, 161 F.3d 77, 85 (1st Cir. 1998). Furthermore, the factors above are not exhaustive; the Court can consider whether "expert testimony [was] prepared solely for purposes of litigation, as opposed to testimony flowing naturally from an expert's line of scientific research or technical work." *Johnson v. Manitowoc Boom Trucks, Inc.*, 484 F.3d 426, 434 (6th Cir. 2007).

Throughout this analysis, a district court exercises a "gatekeeping responsibility." *Daubert*, 509 U.S. at 597. But this gatekeeping function is not intended to displace the jury or the adversarial system: "Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." *Id.* at 596. Importantly, the Federal Rules Advisory Committee explicitly recognized that "'[w]hen facts are in dispute, experts sometimes reach different conclusions based on competing versions of the facts. The emphasis in the amendment on 'sufficient facts or data' is not intended to authorize a trial court to

exclude an expert's testimony on the ground that the court believes one version of the facts and not the other.'" *Gonzalez Prod. Sys. v. Martinrea Int'l Inc.*, Case No. 13-cv-11544, 2015 U.S. Dist. LEXIS 106480, at *25 (E.D. Mich. Aug. 13, 2015) (quoting Fed. R. Evid. 702 Advisory Committee Notes, 2000 amends.).

Consequently, "[w]hen, as here, the parties' experts rely on conflicting sets of facts, it is not the role of the trial court to evaluate the correctness of facts underlying one expert's testimony." *Micro Chem., Inc. v. Lextron, Inc.*, 317 F.3d 1387, 1392 (Fed. Cir. 2003). Courts have repeatedly cautioned that "[t]he fact-finder is entitled to hear [an expert's] testimony and decide whether it should accept or reject that testimony after considering all factors that weigh on credibility, including whether the predicate facts on which [the expert] relied are accurate." *Pipitone v. Biomatrix, Inc.*, 288 F.3d 239, 250 (5th Cir. 2002).

Ultimately, as the Sixth Circuit put it: "A review of the caselaw after *Daubert* shows that the rejection of expert testimony is the exception rather than the rule." *In re Scrap Metal Antitrust Litig.*, 527 F.3d at 530 (citing Fed. R. Evid. 702 advisory committee's note, 2000 amend.). This is a case to follow the general rule: Exclusion of Dr. Specht's testimony is manifestly improper and any further testing of his methodology and opinions is best suited for cross-examination and careful instruction of the jury by the Court.

B. Dr. Specht employed a reliable methodology for measuring bone lead in children.

The main focus of VNA's motion is its challenge to Dr. Specht's use of a pXRF device to test the Plaintiffs. To hear VNA tell it, pXRF is unacceptably inaccurate and thoroughly refuted by Dr. Specht's own peer-reviewed studies. VNA's argument lacks any merit, and the Court should permit Dr. Specht to testify. Each of the four factors from *Daubert* weighs in favor of permitting Dr. Specht to testify. His theory is testable and capable of repetition; he has routinely published his results in peer-reviewed journals; although his methodology necessarily bakes in a degree of "uncertainty," it has not been shown to have a substantial error rate; and pXRF is generally accepted in the relevant scientific community.

1. Dr. Specht's pXRF testing is testable and has been tested.

First, pXRF is testable. "Ordinarily, a key question to be answered in determining whether a theory or technique is scientific knowledge that will assist the trier of fact will be whether it can be (and has been) tested." *Daubert*, 509 U.S. at 593. "'The criterion of the scientific status of a theory is its falsifiability, or refutability, or testability.'" *Id.* (quoting Karl Popper, *Conjectures and Refutations: The Growth of Scientific Knowledge* 37 (5th ed. 1989)).

To be sure, "[t]he question on the table is whether a method can be 'assessed for reliability,' not whether it always gets it right." *Gissantaner*, 990 F.3d at 464 (citing Fed. R. Evid. 702 Advisory Committee Notes, 2000 Amendments; and

United States v. Bonds, 12 F.3d 540, 558–59 (6th Cir. 1993)). "Disputes about the 'adequacy of the [theory's] testing' or about the 'accuracy of [a theory's] results,' generally speaking, provide grist for adversarial examination, not grounds for exclusion." *Id.* (quoting *Bonds*, 12 F.3d at 559). As the Advisory Committee's note explains: The testability factor asks "whether the expert's theory can be challenged in some objective sense, or whether it is instead simply a subjective, conclusory approach that cannot reasonably be assessed for reliability." Fed. R. Evid. 702, Advisory Committee Notes, 2000 Amendments.

Here, most of Dr. Specht's deposition concerned the testing that has occurred. *See Gissantaner*, 990 F.3d at 464. The gravamen of VNA's motion is actually a claim that the testing has shown that the pXRF is not accurate enough for VNA's liking. Thus, this is not the kind of case where a proposed expert's testimony fails the testability factor, such as when "[n]obody . . . has ever . . . tested" the expert's theory. *See Wilden v. Laury Transp., LLC*, 901 F.3d 644, 649 (6th Cir. 2018).

The Sixth Circuit's discussion of the testability factor in *Bonds* is illustrative. There, the government proffered DNA evidence, which the defendants argued was inadmissible under *Daubert. See Bonds*, 12 F.3d at 557–59. Yet, as the Court explained, the testing factor was satisfied notwithstanding the fact that the testing had shown "serious deficiencies" in the DNA testing methodology:

> Defendants vociferously dispute the accuracy of the match results and the adequacy of the testing done, and in refutation have presented

> evidence about deficiencies in both the results and the testing of the results. Thus, it appears that by attempting to refute the FBI's theory and methods with evidence about deficiencies in both the results and the testing of the results, the defendants have conceded that the theory and methods can be tested. The dispute between the Government and the defendants is over how the results have been tested, not over whether the results can be or have been tested.

Bonds, 12 F.3d at 559.

Here, Dr. Specht testified that it would be easy to replicate or test his results: Anybody who wanted to test his results "would need the XRF spectra, a MATLAB license, and then the respective code that is used in order to do the analyses." Ex. 3, Specht Dep., at 494:22–24. Though, VNA's argument isn't really that Dr. Specht's theory or results can't be tested; rather, VNA's argues that "'[n]o one else' in the world has access" to Dr. Specht's specific software code modifications. *See* VNA Br. at 20 (quoting Ex. 3, Specht Dep., at 499:13–21). But that isn't what the testability inquiry requires; rather, the testability factor asks whether "[s]omeone else using the same data and methods [would] be able to replicate the result." *Zenith Elecs. Corp. v. WH-TV Broad. Corp.*, 395 F.3d 416, 419 (7th Cir. 2005).

Courts have rejected this type of argument before. In *Dzielak v. Whirlpool Corp.*, the defendants argued that plaintiff's expert's "analysis cannot be replicated because ASEMAP is a proprietary methodology that employs an undisclosed algorithm." *Dzielak v. Whirlpool Corp.*, Civ. No. 2:12-0089, 2017 U.S. Dist. LEXIS 39232, at *14 (D.N.J. Mar. 17, 2017). But, like MATLAB, ASEMAP "is available

to anyone who purchases a software license." *Id.* at *16. Moreover, although VNA mentioned the settings at the deposition, it never followed up on that request or "moved to compel" Dr. Specht to produce them. *See id.* Thus, like the defendants in *Dzielak*, VNA has "never purchased a license, sought discovery of the source code, or shown any inclination to reproduce Dr. Sukumar's analysis." *Id.* at *20.

More importantly, VNA's argument that "no one else" had access to Dr. Specht's settings is baseless. For one thing, the entire argument is undercut by the heavy reliance they place on various objectors' complaints about bone lead testing. *See* VNA Br. at 26. Conspicuously absent is a claim that VNA attempted to perform any analysis of its own. This is crucial: Dr. Specht testified that the settings were identified in the articles he published. *See* Ex. 3, Specht Dep., at 496:12–22. "[A]nother scientist [could] take the device and then modify it to the settings that [Dr. Specht] describe[d] in [his] publications." *Id.* at 496:23–497:5. And it bears reiterating, that even if VNA had some good faith basis for skepticism in that statement, it never followed up on its request to obtain Dr. Specht's settings.

Accordingly, this this *Daubert* factor favors finding pXRF is reliable.

2. VNA concedes that pXRF testing has been subjected to peer review several times.

Second, as VNA repeatedly concedes (*see, e.g.*, VNA Br. at 11, 12, 19), Dr. Specht's pXRF methodology has been subjected to peer review. "Subjecting a new technology to 'peer review and publication' offers another measure of reliability."

Gissantaner, 990 F.3d at 464 (quoting *Daubert*, 509 U.S. at 593). "The 'key' is whether 'the theory and procedures have been submitted to the scrutiny of the scientific community.'" *Id.* (quoting *Bonds*, 12 F.3d at 559).

Importantly, "publication in a peer-reviewed journal alone typically satisfies this *Daubert* inquiry" because "publication itself is noteworthy in scientific scholarship." *Id.* at 464–65. After all, "[p]eer review . . . involves 'anonymously reviewing a given experimenter's methods, data, and conclusions on paper.'" *Id.* at 465 (quoting *United States v. Mitchell*, 365 F.3d 215, 238 (3d Cir. 2004)). "If experts 'have other scientists review their work' and if the other scientists have the chance to identify any methodological flaws, that usually suffices." *Id.* (quoting *Mitchell v. Gencorp Inc.*, 165 F.3d 778, 784 (10th Cir. 1999)). "When scientific research is accepted for publication by a reputable journal following the 'usual rigors of peer review,' it represents 'a significant indication that it is taken seriously by other scientists, i.e., that it meets at least the minimal criteria of good science.'" *Id.* (quoting *Daubert v. Merrell Dow Pharms.*, 43 F.3d 1311, 1318 (9th Cir. 1995)).

VNA's repeated concessions that Dr. Specht's methodology has been subjected to independent peer review publication several times are dispositive, and the Court should deny VNA's motion. *See Gissantaner*, 990 F.3d at 464–65. VNA argues that peer review in this instance has shown Dr. Specht's methodology to be unsound. *See* VNA Br. at 11–21. It doesn't (and more that in a moment), but more

importantly, that isn't the standard under *Daubert*'s peer review factor.[12] Even when peer review takes an "unfavorable view" of the methodology, the peer review factor is satisfied and weighs in favor of admitting the expert's testimony. *See United States v. Romero-Lobato*, 379 F. Supp. 3d 1111, 1119 (D. Nev. 2019).

As the Sixth Circuit has emphasized, "'flaws in methodology' uncovered by peer review do not equate to a lack of scientific validity, since the methods may be based on scientific principles and the alleged flaws go merely to the weight, not the admissibility, of the evidence and the testimony." *Bonds*, 12 F.3d at 559; *accord Whirlpool Props., Inc. v. LG Elecs. U.S.A., Inc.*, Case No. 1:03-cv-414, 2006 U.S. Dist. LEXIS 1378, at *9 (W.D. Mich. Jan. 10, 2006) ("Even assuming an error in methodology, 'errors in methodology [] properly go to the weight of the evidence . . . .'" (quoting *Schering Corp. v. Pfizer, Inc.*, 189 F.3d 218, 228 (2d Cir. 1999))).

But let's be clear: The peer review of Dr. Specht's pXRF methodology hasn't shown it to be invalid. At most, the peer reviewed literature VNA focuses on showed that there was a modest decline in accuracy for testing conducted *using previous specifications in 2016*. *See* Ex. 3, Specht Dep. at 276:16–278:14 (testing for the 2019 article was conducted in 2016). In 2016, Dr. Specht and his team "had not optimized the methodology." *Id.* at 258:9–259:4. As Dr. Specht explained: If they had used three minutes rather than two, they "would have been able to identify a much

[12] At most, those findings would bear on the "rate of error" factor.

stronger association." *Id.* at 259:5–12. As he said later when VNA attempted to raise the issue again, the "procedural differences account for a lot of that." *See id.* at 298:5–22; *see also id.* at 300:6–18.

So, despite knowing better, VNA repeatedly takes conclusions from older testing—before Dr. Specht improved the pXRF methodology—and imagines that they apply to the testing done in late 2019 in this case. They don't; and VNA's heavy emphasis on results obtained with the older procedural settings (and complete lack of any mention of the current procedural settings) shows there is no credible challenge regarding the admissibility of testing done with the settings Dr. Specht employed in Flint. Accordingly, the many instances of peer review of Dr. Specht's methodology weigh strongly in favor of permitting him to testify.

3. The built-in measure of uncertainty in pXRF testing is exceptionally low, and each Plaintiff's bone lead measurement exceeded overall uncertainty.

Third, there is no serious "error rate" to pXRF testing. *Daubert*'s error rate factor "looks to the error rate of the technology and to whether the scientific community has established standards that [scientists in the field] can use to mitigate the risk of error." *Gissantaner*, 990 F.3d at 465.

The factor is primarily focused on whether the expert "identifie[s]" the error rate and takes it into account. *See Mitchell*, 365 F.3d at 241 ("We therefore accept that the error rate has been sufficiently identified to count this factor as strongly

favoring admission of the evidence.").[13] The actual error rate is somewhat less significant. *See Bonds*, 12 F.3d at 560 (permitting expert to testify where "[t]he FBI did conduct internal proficiency tests to determine a rate of error and calculated a rate of error," even though "the magistrate found these proficiency tests to have 'serious deficiencies'" and the appellate court found them "troubling").

After all, error rates are, as a general matter, endemic not just to scientific evidence but all evidence. *See Gissantaner*, 990 F.3d at 465. And all error rates, including pXRF's measure of uncertainty and the "margin of error" commonly used in other litigations, are generally matters of weight, not admissibility. *See Mass. Mut. Life Ins. Co. v. Residential Funding Co., LLC*, 989 F. Supp. 2d 165, 174 (D. Mass. 2013) ("The margin of error speaks to the persuasive power of the sample, not its admissibility." (quotation marks omitted)); *see also United States v. Brady*, 595 F.2d 359, 363 (6th Cir. 1979) ("[T]he lack of certainty went to the weight to be assigned to the testimony of the expert, not its admissibility, and defense counsel did a creditable job of arguing to the jury that it should be assigned little weight.").

Since error rates generally (and the measure of uncertainty here in particular) at most affect the weight of evidence, other measures—cross-examination, contrary evidence, and careful instruction on the burden of proof—all furnish better means of

[13] To be sure, even an "uncertain rate of error" is not necessarily a basis to exclude the expert. *See Ruiz-Troche*, 161 F.3d at 85.

ventilating the issue of the margin of error. As the First Circuit explained of methodology and theory with an "uncertain rate of error": "[I]t should be tested by the adversary process—competing expert testimony and active cross-examination—rather than excluded from jurors' scrutiny for fear that they will not grasp its complexities or satisfactorily weigh its inadequacies." *Ruiz-Troche*, 161 F.3d at 85.

For this reason, even very high margins of error generally do not render testimony inadmissible. *See Mass. Mut. Life Ins. Co.*, 989 F. Supp. 2d at 174. There, one party argued that the other party's expert "± 10 percentage point margin of error is *twice as wide as the typical margin of error in the litigation context*," and "that [the expert's] reports in other mortgage-backed securities actions have employed a ± 5 percentage point margin of error." *Id.* (emphasis added).[14] However, the court permitted the expert to testify, recognizing that "the ± 10 percentage point margin of error does not render [the expert's] methodology unreliable." *Id.*

[redacted]

[14] Even that margin of error was itself more than twice the "± 2 percentage point margin of error in . . . quality control guidelines" used by the pertinent government agencies in contexts "outside litigation." *Id.*

[redacted]

What's more, the measure of uncertainty is very low, both in general and particularly with respect to the four Bellwether Plaintiffs. *See* Ex. 3, Specht Dep., at 133:12–18 (noting an uncertainty level "over 10 or much greater than 15" would be concerning). Since none of the Plaintiffs' scans were "lower than [their respective] uncertainty," there is no reason to suspect that the uncertainty have any significant "impact on the measurement." *Id.* at 133:18–21. On the contrary, each Plaintiff's bone scan is "higher than the uncertainty" there is every reason to be "confident in the results." *Id.* at 133:21–24.

VNA claims that two previous peer-reviewed articles (Dr. Specht's 2016 and 2019 articles) published show that his "own research found that the use of pXRF on children has too high of an error rate to be reliable at this point." *See* VNA Br. at 22 (citing Ex. 5, Specht Lin 2016, at 7; Ex. 11 Specht Dickerson 2019, at 8).[15] Notably, neither concludes that pXRF's error rate as to children is too high. Rather, both simply acknowledge that, as of 2016, some further research was needed. That

[15] VNA had a burden to attempt to prove the existence of error rates and has failed to provide any other evidence of error rates. *See Mitchell*, 365 F.3d at 240; *see also United States v. Sullivan*, 246 F. Supp. 2d 700, 703 (E.D. Ky. 2003).

research has been done, and as Dr. Specht testified, the pXRF has been fully verified since—including for children. Ex. 3, Specht Dep., at 278:11–14; 23:2–11.

Nevertheless, VNA is wrong for two reasons. First, VNA is—at best—referring to the tendency of the uncertainty level to increase when soft tissue is thicker than 5 mm. *See id.* at 103:23-104:24. VNA believes that its stray citation to an article it claims shows children generally have soft tissue thicknesses in excess of 5 mm requires the Court to find that Dr. Specht's methodology is unsound. See VNA Br. at 23. VNA ignores that Dr. Specht found very low levels of uncertainty for each of the Plaintiffs, which are actually consistent with lower tissue thicknesses. *See* Ex. 1, Specht Report., at 14, 16, 17, 19; Ex. 3, Specht Dep., at 492:10–493:23.

Moreover, the uncertainty measure is based on multiple factors, including tissue thickness and net lead levels, and is automatically derived by the pXRF device and MATLAB software based on feedback obtained during the scan. Ex. 3, Specht Dep., at 131:10–133:9. Given that uncertainty is a product of more than just soft tissue thickness—and that VNA never sought discovery as to the thickness of Plaintiffs' soft tissue at the tibia—VNA's abstract musings as to soft tissue thickness are, at most, fodder for (tepid) cross-examination.

Second, and more importantly, VNA evidently overlooks the impact of Dr. Specht's modifications of the pXRF standard operating procedures since the testing for those two studies was conducted. As above, the testing for those articles was

completed in 2016, *see* Ex. 3, Specht Dep., at 276:16–278:14, using "two minutes rather than three minutes in the procedures," *id.* at 258:9–259:4, a fact which "account[s]" for the 2016 results, *see id.* at 298:5–22; *see also id.* at 300:6–18. If they had used three minutes rather than two, there would have been "a much stronger association." *Id.* at 259:5–12. VNA actually admits that "[w]ith each research paper, Dr. Specht has continued to adjust the calibration and measurement time of his pXRF device," but attempts to spin it as showing Dr. Specht's methodology is unscientific and unreliable. *See* VNA Br. at 22.

Yet, contrary to VNA's protestations, the even-lower levels of uncertainty Dr. Specht has achieved with improved calibrations and measurement time *actually* show the pXRF methodology he employed in testing the Plaintiffs here is highly reliable.[16] *See Gissantaner*, 990 F.3d at 466 ("One explanation for the low error rate is the existence of standards to guide the use of STRmix and other probabilistic genotyping software, for the two are '[c]losely related.'"

[16] VNA's argument that the recent experimentation with five-minute testing could achieve a still-lower error rate might be a fine a question for cross-examination, but it doesn't render Dr. Specht's methodology scientifically unsound in the slightest. *See In re TMI Litig.*, 193 F.3d 613, 665 (3d Cir. 1999) ("The test of admissibility is not whether a particular scientific opinion has the best foundation, or even whether the opinion is supported by the best methodology or unassailable research. Rather, the test is whether the 'particular opinion is based on *valid* reasoning and *reliable* methodology.'" (quoting *Kannankeril v. Terminix Int'l Inc.*, 128 F.3d 802, 806 (3d Cir. 1997)).

More to the point, the story of virtually any technology is one of refinement and continuous improvement over time. To take another example, compare the "serious deficiencies" of the DNA testing in the Sixth Circuit's 1993 opinion in *Bonds* with the extraordinarily low error rate of DNA testing software in the Sixth Circuit's 2021 opinion in *Gissantaner*. *Compare Bonds*, 12 F.3d at 560, *with Gissantaner*, 990 F.3d at 465–66. When *Bonds* was decided in 1993, DNA testing was rather novel (it was first used only a few years before), and the lower court permitted the prosecution's expert to testify that there was a "1 in 35,000" chance that someone other than the defendant was guilty. *See* 12 F.3d at 551. Nearly three decades later, when *Gissantaner* was decided, DNA testing was well established, and the risk of a similar false positive was "49 million to 1." *See* 990 F.3d at 462.

Accordingly, this factor weighs in favor of permitting Dr. Specht to testify.

4. Dr. Specht's pXRF testing is generally accepted in the relevant scientific community.

Fourth, pXRF has gained general acceptance in the "relevant scientific community." *Gissantaner*, 990 F.3d at 466. As the *Daubert* Court explained,

> Nothing in the text of this Rule [702] establishes "general acceptance" as an absolute prerequisite to admissibility. Nor does respondent present any clear indication that Rule 702 or the "Rules as a whole were intended to incorporate a "general acceptance" standard. The drafting history makes no mention of *Frye*, and a rigid "general acceptance" requirement would be at odds with the "liberal thrust" of the Federal Rules and their "general approach of relaxing the traditional barriers to 'opinion' testimony."

Daubert, 509 U.S. at 588 (quoting *Beech Aircraft Corp. v. Rainey*, 488 U.S. 153, 169 (1988)). Likewise, in the Sixth Circuit's words: "Neither newness nor lack of absolute certainty in a test suffices to render it inadmissible in court. Every useful new development must have its first day in court." *Bonds*, 12 F.3d at 561 (quoting *United States v. Stifel*, 433 F.2d 431, 438 (6th Cir. 1970)).

To be sure, "'general acceptance' can yet have a bearing on the inquiry" of whether proposed testimony is reliable, and although a "'reliability assessment does not require" the Court to consider a scientific theory's general acceptance in the relevant scientific community, "it does permit" the Court to consider the "particular degree of acceptance within [the relevant scientific] community.'" *Daubert*, 509 U.S. at 594 (quoting *United States v. Downing*, 753 F.2d 1224, 1238 (3d Cir. 1985)). That said, as the Sixth Circuit recently put it, "[t]he question for debate is 'general acceptance,' not uniform acceptance within the community." *Gissantaner*, 990 F.3d at 466. Indeed, the "general acceptance" does not require showing a "consensus" in favor of the expert's methodology or even "majority" support. *Bonds*, 12 F.3d at 562. "Only when a theory or procedure does not have the acceptance of most of the pertinent scientific community, and in fact a substantial part of the scientific community disfavors the principle or procedure, will it not be generally accepted." *Id.*

Correspondingly, that the "relevant scientific community" is "small" does not deprive a methodology of "general acceptance." *See People v. Kogut*, 10 Misc. 3d 314, 319–20 (N.Y. Sup. Ct. Nassau Cty. 2005) (permitting expert testimony under a *Frye* "general acceptance" standard where "[t]he methodology for identifying postmortem hair banding was published in 1988 and has been subject to peer review, albeit within a small community"); *United States v. Jones*, 965 F.3d 149, 161–62 (2d Cir. 2020) (holding that a proposed expert's methodology was "generally accepted" even though the expert's laboratory was the "only laboratory" to practice it.)

Here, Dr. Specht testified that pXRF testing was generally accepted. "Bone lead I feel like is a very set measurement, methodology now. We've done so many papers on it that it's fairly widely understood to be something that's possible to do with this device." Ex. 3, Specht Dep., at 62:22–63:3. When VNA's counsel argumentatively asked if pXRF testing was "novel," Dr. Specht responded:

> If you just mean [whether] it's accepted in the scientific community, then it was probably—in my mind, it was accepted as soon as we published our paper that looked at comparison measurements between the device and the gold standard measurements, which showed that it had a very good agreement between that and the gold standard measurements . . . .

Id. at 63:20–64:3.[17]

[17] VNA attempts to hang its hat on references to KXRF as the "gold standard" and that Dr. Specht's opinions are necessarily unreliable since he used the pXRF technology. *See* VNA Br. at 11. Using the very best technology or

VNA marshals little in response. Generally speaking, it points to an expert's arguably contrary opinion (though not its own expert and not one who will be testifying at trial) and some public conjecture regarding potential health concerns as to bone scans. *See* VNA Br. at 23–27. At the outset, VNA is wrong about what Dr. Hu's testimony shows; after all, Dr. Hu *actually* approves of pXRF testing and agrees that it "been validated as an accurate reproducible scientific instrument," and affirmatively testified that "it has been validated for research." VNA Ex. 7, Hu Dep., at 384:10–18. Indeed, Dr. Hu himself uses pXRF testing in his research. *Id.*

Even assuming Dr. Hu's testimony somehow signifies a serious disagreement about whether pXRF is generally accepted (which it does not), "court records are full of the conflicting opinions of doctors, engineers and accountants, to name just a few of the legions of expert witnesses." *Bonds*, 12 F.3d at 561–62 (quoting *Stifel*, 433 F.2d at 438). "[T]he Court's role under Rule 702 is to ensure that expert testimony reflects accepted standards within the relevant scientific and business communities—it is not to serve as an umpire between competing subsets of a given community." *In re Johnson & Johnson Derivative Litig.*, 900 F. Supp. 2d 467, 492 (D.N.J. 2012). Thus, as is true for the other *Daubert* factors, Dr. Hu's mild criticism about pXRF's "utility" and comparative "precis[ion]," *see* VNA Br. at 24–25

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methodology, of course, isn't what *Daubert* requires. *See In re TMI Litig.*, 193 F.3d at 665. Moreover, KXRF was the "gold standard" in the 1990s "because it was the only one used." Ex. 3, Specht Dep., at 224:15–225:1.

(quoting VNA Ex. 7, Hu Dep., at 382:7–383:5), are merely the kind of "[d]isputes about specific techniques used or the accuracy of the results generated [that] go to the weight, not the admissibility of the scientific evidence." *Bonds*, 12 F.3d at 561.

"Nor must the science be beyond reproach." *Gissantaner*, 990 F.3d at 466. "[E]ven substantial criticism as to one theory or procedure will not be enough to find that the theory/procedure is not generally accepted." *Bonds*, 12 F.3d. at 562. Thus, the modest caveats to the approval by a single scientist who also uses the technology in research settings—who VNA hasn't retained and who won't be testifying at trial—are not "substantial criticism" and do not establish that "a substantial part of the scientific community disfavors" pXRF testing. *See id.*

While the Sixth Circuit's observations in *Bonds* address criticisms of methodology, they undoubtedly apply just as strongly to the asserted health concerns to that do not affect the validity of the scientific methodology.[18] After all, the general public, as well as general public health advocates in this case, are not in Dr. Specht's "relevant scientific community." *Daubert*, 509 U.S. at 594.

Accordingly, this factor therefore weighs in favor of reliability.

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[18] The x-rays from the pXRF device "give a small radiation exposure, which is equivalent to that of standing outside for about 9 hours with natural cosmic sources of radiation or equivalent to 1/3rd of a single dental x-ray." Ex. 1, Specht Report, at 6 (citing A.J. Specht & X. Zhang et. al., *A Dosimetry Study of Portable X-ray Fluorescence in Vivo Metal Measurements*, 116(5) Health Phys. 590-98 (2019). ("Specht Zhang 2019")).

5. Dr. Specht's pXRF testing is direct outgrowth of his preexisting research.

Finally, Dr. Specht's pXRF testing of the Plaintiffs here is a natural outgrowth of, and direct application of, his prior research. In the Sixth Circuit, a district court can consider whether "expert testimony [was] prepared solely for purposes of litigation, as opposed to testimony flowing naturally from an expert's line of scientific research or technical work." *Johnson*, 484 F.3d at 434.

Attempting to force a square peg into a round hole, VNA suggests that Dr. Specht's pXRF bone lead testing was "prepared solely for litigation." VNA Br. at 27 (quoting *Newell Rubbermaid, Inc. v. Raymond Corp.*, 676 F.3d 521, 527 (6th Cir. 2012)). VNA pays the argument short shrift—and for good reason. Its argument is completely wrong-headed: This factor *actually* weighs heavily in favor of reliability.

As the Sixth Circuit explained: "If it is clear that a proposed expert's testimony flows naturally from his own current or prior research (or field work), then it may be appropriate for a trial judge to apply the Daubert factors in somewhat *more lenient* fashion." *Johnson*, 484 F.3d at 435 (emphasis added). Doing so is "in line with the notion that an expert who testifies based on research he has conducted independent of the litigation 'provides important, objective proof that the research comports with the dictates of good science.'" *Id.* (quoting *Daubert v. Merrell Dow Pharms.*, 43 F.3d 1311, 1317 (1995) (*Daubert II*)).

Here, Dr. Specht's testing of the Plaintiffs and the conclusions in his report are a direct outgrowth from, and application of, his prior research which began long before the Flint litigation began and certainly before Dr. Specht was retained as an expert. Dr. Specht is not doing anything other than applying his ordinary pXRF testing methodology to the Plaintiffs. *See Kumho Tire,* 526 U.S. at 152 (*Daubert*'s objective "is to make certain that an expert . . . employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field"). It is thus "clear" that Dr. Specht's opinions "flow[] naturally from his own current or prior research" and "field work." *Johnson*, 484 F.3d at 435.

The factors above strongly and unanimously favor permitting Dr. Specht to testify no matter how they are applied, but Sixth Circuit precedent calls for, if anything, applying them in a "somewhat more lenient fashion" here. *Id.*

C. Dr. Specht's opinions regarding the lead in Plaintiffs' bones are reliable.

Likewise, Dr. Specht's opinions based on pXRF testing are reliable. Importantly, Dr. Specht's opinions are simply relating his measurements of Plaintiffs' bone lead and comparing those results to other studies. While VNA purports to separately challenge Dr. Specht's opinions, those arguments are merely a rehashing of the arguments it made with respect to pXRF testing more generally. For instance, VNA thinks his methodology isn't sound or that he can't rely on his previous studies. All of the reasons above are good reasons to reject VNA's

challenges; after all, Dr. Specht's use of pXRF testing is reliable, and VNA's arguments go at most to the weight, not the admissibility, of testimony. *See Bonds*, 12 F.3d at 559. Accordingly, the Court should deny VNA's motion.

1. Dr. Specht's opinions flow directly from his own pXRF research, testing, and methodology, and his comparisons are reliable.

As above, Dr. Specht's testing methodology is a "natural outgrowth" of his prior research, testing, and field work. Moreover, Dr. Specht's testimony will directly communicate the results of his reliable and scientifically valid measurements of Plaintiffs' bone lead using pXRF technology. He will convey the significance of those results by comparing them with other studies of bone lead levels in populations with known significant exposures. For example, in his report, Dr. Specht compares the Plaintiffs' bone lead levels with those of his China studies, as well as McNeill's study of children in Ontario. Ex. 1, Specht Report, at 7. He can reliably testify that Plaintiffs' bone lead measurements are "more consistent with that of lead poisoned children in the study in China" even though blood lead levels in Flint tend to be "only slightly elevated with respect to the CDC reference levels." *Id.* Notably, the children in the China study were ingesting "100% lead powder" as a form of medicine. *Id.*; *see also* Ex. 3, Specht Dep. at 283:22–284:5.

VNA challenges to Dr. Specht's comparisons are meritless. First, VNA claims that Dr. Specht was required to establish a "baseline" for bone lead levels. *See* VNA

Br. at 28–30.[19] VNA believes the fact no other study explicitly defined an "elevated" bone lead level requires the Court to exclude Dr. Specht's opinion.[20] Yet, the comparisons are helpful notwithstanding an absence of a regulatorily defined "elevated" level. After all, the characteristics of exposure of the subject populations of those previous studies themselves furnish an adequate basis for comparison by the jury. As an example, Dr. Specht was easily able to identify comparison studies involving "populations where there was leaded gasoline exposure." *See* Ex. 3, Specht Dep., at 433:13–19. He considered lead gasoline exposure to be a "persistent exposure." *Id.* at 433:19–21. "In previous studies of leaded gasoline exposure, the age relations were such that leaded gasoline alone would account for measures of bone lead that were greater than 10 but not greater than 20." *Id.* at 434:15–19.[21]

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[19] As a part of this argument, VNA claims that "Dr. Specht admits that there are no reliable benchmarks." VNA Br. at 29. VNA doesn't provide a citation for this sentence because it is utterly false.

[20] At a minimum, of course, as Dr. Specht testified in his deposition, any bone lead level "above zero" would reflect "an exposure." Ex. 3, Specht Dep., at 431:24–432:12. That alone would be enough to be helpful for a jury, since (as described further below) VNA has telegraphed an intent to argue that the Plaintiffs were never exposed to lead at all. But more importantly, given that the CDC now recognizes that there is no safe amount of lead exposure for a child, an "elevated" is "anything above [zero]." Ex. 3, Specht Dep., at 451:20–24.

[21] VNA's claim that Dr. Specht "conceded that the literature 'wouldn't be relevant' to children, *see* VNA Br. at 30 (citing Ex. 3, Specht Dep., at 432:1–436:3), is deliberately misleading. He didn't make any such concession; rather, he testified that the reference values were relevant, but that the "adult exposures . . . wouldn't be relevant in the cases of the Bellwether cases." Ex. 3, Specht Dep., at 432:9–12.

As it did elsewhere, VNA again attempts to impugn Dr. Specht's 2016 and 2019 studies, which used a previous methodology. As Plaintiffs showed repeatedly above, the refinements in methodology show that the bone lead testing in Flint is highly accurate. More importantly, though, VNA's efforts to cast doubt on Dr. Specht's comparison to the 2016 and 2019 China studies miss the mark: Those studies involved children with known exposures and reliably measured bone lead levels (at a minimum with KXRF, which VNA does not challenge).

VNA's efforts to quibble with the particulars of numbers of these various studies, whether Dr. Specht's comparisons to his studies in China, his comparison to gasoline exposures, or his comparison to children all miss the point of *Daubert*'s reliability analysis. Under Sixth Circuit law, an expert may testify unless the numbers are "pull[ed] . . . from thin air," s*ee Jahn v. v. Equine Servs., PSC*, 233 F.3d 382, 391 (6th Cir. 2000); *accord In re Scrap Metal Antitrust Litig.*, 527 F.3d at 531.

Consequently, VNA's disputes as to the applicability of studies are the kind of dispute is quintessentially ill-suited to a *Daubert* determination. *See In re Johnson & Johnson Talcum Powder Prods. Mktg., Sales Practices & Prods. Litig.*, Civil Action No.: 16-2738(FLW), MDL No. 2738, 2020 U.S. Dist. LEXIS 76533 (D.N.J. Apr. 27, 2020) ("Distilled to its essence, the dispute between the parties as to whether the studies support the experts' opinions appears to be based on competing interpretations of the studies' results and whether those results support a dose-

response relationship. But, it is not the Court's position as gatekeeper to determine whose interpretation of the studies is correct, as long as the competing interpretations are each rooted in some sound ground.").

2. VNA's other objections to Dr. Specht's opinions are misguided and incorrect.

VNA mounts several objections to Dr. Specht's opinions. None are correct. For instance, VNA claims that Dr. Specht was required to test a control group. VNA Br. at 38.[22] However, the cases VNA cites don't support its proposition. VNA's lead case is illustrative. *Pick v. Am. Med. Sys., Inc.* notes that "courts have rejected case studies as an insufficient basis to decide causation when they lack control groups." 958 F. Supp. 1151, 1161 (E.D. La. 1997) But Dr. Specht isn't using a case study method. Nor would he since he isn't testifying on issues of general causation. *See id.* at 1160 ("Case studies assess general causation . . . .").

Other arguments by VNA are simply disagreements about relevant facts. For example, VNA claims that Dr. Specht's opinion about the half-life of lead in bone is unreliable because other scientific studies prove (in its view) that lead in children has an even longer half-life than in adults. *See* VNA Br. at 3. As VNA admits, Dr.

[22] Never mind that the circumstances—lead in municipal drinking water that went undetected for some time and about which most Flint water users had essentially no choice—renders a control group impossible, or that VNA evidently would not be satisfied with a control group of children from a non-Flint community.

Specht formed his opinion based on his own research. *Id.* at 3.[23] However, VNA believes the Court should take its word for it and rely on three different studies and apparently make a judgement as to which picture of the science is "correct." But this is exactly what *Daubert* and Rule 702 forbid. *See Micro Chem.*, 317 F.3d at 1392; *see also Pipitone*, 288 F.3d at 250 ("The fact-finder is entitled to hear [an expert's] testimony and decide whether it should accept or reject that testimony after considering all factors that weigh on credibility, including whether the predicate facts on which [the expert] relied are accurate.").

Finally, Defendants' reliance on *Dombrowski v. Gould Elecs. Inc.,* 31 F. Supp. 2d 436 (M.D. Pa. 1998) is misplaced. There, plaintiffs sought to use KXRF as "a monitoring procedure does in fact exist that would make the early detection of a disease possible" for those exposed to industrial lead emissions. 31 F. Supp. 2d at 442. The court acknowledged that "that the testimony shows that KXRF testing may detect evidence of lead in the bone structure, and may give readings to that effect," yet was concerned that "the testimony also reveals that there is no set standard against which to compare those trace readings in an effort to detect the possibility of

[23] VNA's accusation that relying on his own (more recent and accurate) studies constitutes "cherry picking" and that he "distorts" them is not simply wrong. More importantly, VNA acknowledges that his reliance is on "his own" studies, *see* VNA Br. at 47. VNA somehow again overlooks that reliance on "his own" previous research actually *confirms* the reliability of his opinions under binding Sixth Circuit precedent. *See Johnson*, 484 F.3d at 435. Notably, not one of the inapposite, out-of-circuit cases VNA cites involves an expert relying on their prior research.

disease or to determine the efficacy of those readings." *Id.* In other words, the plaintiffs in *Dombrowski* wanted KXRF to do too much, which wasn't possible at that time, and so KXRF would not be able to achieve the kind of medical monitoring plaintiffs sought in a reliable way.[24]

Here, however, Plaintiffs will offer Dr. Specht to testify about a very narrow and discrete point: The presence of lead in Plaintiffs' bones. On that score, *Dombrowki* favors admission, not exclusion. *See Dombrowski*, 31 F. Supp. 2d at 442 (acknowledging that, even then, XRF readings may "detect evidence of lead in the bone structure and may give readings to that effect").[25] Rather than testifying about all aspects of causation, Dr. Specht is merely being offered to help show exposure. *Cf. Daubert*, 509 U.S. at 591 ("[S]cientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes.").

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[24] VNA's suggestion that KXRF itself is unreliable is specious. While the *Dombrowski* court did exclude testimony on KXRF testing in the 1990s, in the decades since, KXRF testing has made significant advances, has been verified as a reliable method, and has gained general acceptance in the scientific and legal communities. In fact, a future where efforts are undertaken to "improve and perfect the KXRF instrument and methodology" is precisely what the court in *Dombrowki* expected. *Id.* at 442. Now, decades later, VNA repeatedly refers to KXRF testing as the "gold standard" for measuring bone lead levels. *See* VNA Br. at 1, 4, 5, 15, 23.

[25] And it bears noting that "Rule 702 allows an expert to 'testify in the form of an opinion *or otherwise*.'" *Jesa Enters. v. Thermoflex Corp.*, 268 F. Supp. 3d 968, 973 (E.D. Mich. 2017) (quoting Fed. R. Evid. 702). That means "means that the expert may share his or her special knowledge with the jury in areas that might extend beyond the information known to the average juror." *Id.* (citations omitted)).

Accordingly, Defendants' contention that pXRF testing provides no standard against which to compare Dr. Specht's readings is thus irrelevant and untrue.

II. There is no basis to exclude Dr. Specht's testimony under Federal Rule of Evidence 403.

Separately, VNA contends that Dr. Specht's testimony should be excluded under Rule 403 since Dr. Specht does not attempt to trace the source of lead in Plaintiffs' bones. Of course, Plaintiffs' other experts testify about general and specific causation, and Dr. Specht's testimony is nonetheless highly probative. There is thus no basis at all to exclude or limit Dr. Specht's testimony under Rule 403.

A. Legal standard under Federal Rule of Evidence 403.

Federal Rule of Evidence 403 permits a district court to "exclude relevant evidence if its probative value is substantially outweighed by a danger of one or more of the following: unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence."

Rule 403 also factors into a district court's gatekeeping function with respect to expert testimony under Rule 702. *See Daubert*, 509 U.S. at 595. To satisfy Rule 702's requirement that testimony be helpful to the trier of fact, the sponsor of the expert testimony must establish that there is a "fit" between the proffered expert testimony and "an[] issue in the case." *Id.* at 591. Put another way, "there must be a connection between the scientific research or test result being offered and the disputed factual issues in the case in which the expert will testify." *Pride v. BIC*

Corp., 218 F.3d 566, 578 (6th Cir. 2000). A district court "exercises more control over experts than over lay witnesses." 509 U.S. at 595.

"The test under Rule 403 is not whether the evidence is detrimental, but whether it is so unfairly prejudicial as to substantially outweigh its probative value." *United States v. Weinstock*, 153 F.3d 272, 278 (6th Cir. 1998). The Sixth Circuit has explained that "[u]nfair prejudice 'does not mean the damage to a defendant's case that results from the legitimate probative force of the evidence; rather it refers to evidence which tends to suggest decision on an improper basis.'" *Bonds*, 12 F.3d at 567 (quoting *United States v. Schrock*, 855 F.2d 327, 333 (6th Cir. 1988)); *accord United States v. Mendez-Ortiz*, 810 F.2d 76, 79 (6th Cir. 1986), *cert. denied*, 480 U.S. 922 (1987)). An "improper basis" is "commonly, though not necessarily, an emotional one." *United States v. Hathaway*, 798 F.2d 902, 909 (6th Cir. 1986).

B. Dr. Specht's testimony would not be significantly more prejudicial than probative.

The essence of VNA's argument under Rule 403 is that Dr. Specht's testimony could only admissible if it traced the source of lead he found in Plaintiffs' bones. However, VNA mistakes the narrow scope of Dr. Specht's testimony. He will not be testifying to matters of causation; instead, his anticipated testimony is limited to the results of the pXRF testing. His testimony is highly probative because one of VNA's core arguments is that the Plaintiffs were never lead poisoned, *see* VNA Summary Judgment Br. at 6–13, 91–95, and his testing tends to show that each

Plaintiff has a significant concentration of lead in their bones. Nor is his testimony likely at all to be confusing or unduly prejudicial.

Crucially, VNA tacitly acknowledges the probative value of bone lead testing. Consider VNA's argument that Dr. Specht has a "vested interest in undermining the usefulness of blood-lead testing." VNA Br. at 47 n.9. The claim is outrageous, false, and abusive. But, more importantly, it highlights the importance of why Dr. Specht's testing and testimony will be helpful to the jury. VNA evidently believes that blood-lead testing, as it stands, is good for it and that bone-lead testing would tend to undermine its position that there is no proof that the Plaintiffs have been exposed to lead. Indeed, the stridency of VNA's attacks on Dr. Specht shows that it understands Dr. Specht will offer compelling testimony on what will likely be a core, disputed issue at trial. At trial, the parties will present conflicting evidence and testimony about blood-lead levels. This argument, then, shows why Dr. Specht's testimony has a high degree of probative value.

Indeed, Dr. Specht's testimony would show VNA's argument to be (at best) the kind of bare denial made time and again by defendants in all sorts of settings. If the jury finds Dr. Specht credible, his testimony would on its own refute that argument and shift the focus to other issues, like the dosage of lead in Flint's water and its effect on the Plaintiffs after they consumed it. In that regard, his testimony would certainly be averse to VNA. Yet, it bears recalling that evidence that tends to

inculpate defendants is routinely admitted. "If all evidence adverse to a defendant was subject to exclusion under Rule 403, then no . . . evidence [against them] would ever be deemed admissible." *Weinstock*, 153 F.3d at 278.

Accordingly, Dr. Specht's testimony is highly probative, and the probative value of his testimony strongly outweighs any faint prejudice VNA imagines. There is no reason to exclude Dr. Specht's testimony.

C. Far better means than exclusion exist for avoiding prejudice.

Finally, exclusion is a disproportionate remedy for any faint (and purely theoretical) prejudice or confusion that VNA imagines. Under Rule 403, the Court can obviate the risk "that the jury might misunderstand" by requiring the evidence to be "describe[d] . . . in a way that will not generate 'unfair prejudice' or 'mislead[] the jury.'" *Gissantaner*, 990 F.3d at 470 (quoting Fed. R. Evid. 403). Moreover, the Court has the power to instruct the jury as to which purposes testimony or evidence may be considered. *Cf. Williams*, 567 U.S. at 80–81.

To be clear, Plaintiffs do not believe a cautioning instruction is necessary. In opening, Plaintiffs will tell the jury—as they did the Court, above—what they mean for each expert to explain. Similarly, they will reiterate to the jury how their experts' testimony fits together to prove causation in closing. And, in between, Plaintiffs have no intention of having Dr. Specht offer testimony outside the scope of his expertise

and testing. However, if the Court disagrees and believes that there is a risk of confusion or prejudice, an instruction is a better remedy than exclusion.

CONCLUSION

Accordingly, the Court should deny VNA's motion to exclude Dr. Specht.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Renner K. Walker, hereby certify that on July 29, 2021, the foregoing brief and attached exhibits were served on all counsel of record via the court's ECF system.

/s/ Renner K. Walker
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